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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/405,046	09/27/1999	THOMAS MEADE	A-58634-6/RF	9059

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DORSEY & WHITNEY LLP
 FOUR EMBARCADERO CENTER
 SUITE 3400
 SAN FRANCISCO, CA 94111-4187

EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/405,046

Applicant(s)

MEADE ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-30 and 32-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 22-30 and 32-58 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

RESTRICTION INTO GROUPS

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 22, 23 30, 32, 33, 34, 41-51 and 58, drawn to a MRI composition and use thereof wherein the protease is a caspase, classified in class 424, subclass 9.3.
 - II. Claims 22, 24 30, 32, 33, 35, 41-50, 52, and 58, drawn to a MRI composition and use thereof wherein the protease is a interleukin-1 beta-converting enzyme, classified in class 424, subclass 9.3.
 - III. Claims 22, 25 30, 32, 33, 36, 41-50, 53, and 58, drawn to a MRI composition and use thereof wherein the protease is a cysteine, classified in class 424, subclass 9.3.
 - IV. Claims 22, 26 30, 32, 33, 37, 41-50, 54, and 58, drawn to a MRI composition and use thereof wherein the protease is a serine, classified in class 424, subclass 9.3.
 - V. Claims 22, 27 30, 32, 33, 38, 41-50, 55, and 58, drawn to a MRI composition and use thereof wherein the protease is a calpain, classified in class 424, subclass 9.3.
 - VI. Claims 22, 28 30, 32, 33, 39, 41-50, 56, and 58, drawn to a MRI composition and use thereof wherein the protease is a cathepsin, classified in class 424, subclass 9.3.

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- VII. Claims 22, 29 30, 32, 33, 40, 41-50, 57, and 58, drawn to a MRI composition and use thereof wherein the protease is a metalloproteinase, classified in class 424, subclass 9.3.
- VIII. Claims 22, 30, 32, 33, 41-50 and 58, drawn to a MRI composition and use thereof wherein the protease is not one from Groups I-VII above, classified in class 424, subclass 9.3.

Note: Claims appearing in more than one group will be examined only to the extent that they read on the elected invention.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions required the presence of specific peptide-protease combinations in order to work. For example, if the peptide contains a cysteine residue, then the use of a cysteine protease would be appropriate. However, since the proteases are different for each group, the modes of operation, function, and effects of each group is distinct since it is peptide sequence dependent.

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3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

ELECTION OF SPECIES

4. Claims 22-30 and 32-58 are generic to a plurality of disclosed patentably distinct species comprising peptides. In particular, it is noted that depending upon the peptide sequence attached to the metal-chelator-linker complex, the protease will vary. Thus, the type of protease to be used which may be selected from caspase, interleukin-1 beta-converting enzyme, cysteine, serine, calpain, cathepsin, and metalloproteinase depends upon specific peptide sequences.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Notes: (1) *The Examiner respectfully requests that Applicant elect a specific peptide sequence compatible with the protease selected from the group above.*

Applicant is respectfully requested to submit the specific sequence of the selected peptide.

(2) If Applicant elects Group VIII above, it is respectfully requested that the protease be identified in addition to the peptide sequence.

5. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

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case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. A telephone call was not made to request an oral election to the above restriction requirement due to the complexity of the instant invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

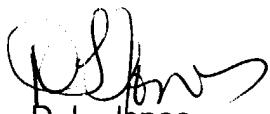
8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


D. L. Jones
Primary Examiner
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April 15, 2004